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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,067	01/22/2002	Hellen Chaya Greenblatt	CV0110A	6138

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/054,067	GREENBLATT ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-8 are drawn to a method for treating and preventing diarrheal symptoms wherein the method comprises administering to the subject an effective amount of egg product comprising one or more anti-diarrheal agents that comprise a substance other than an antibody. The written description in this case only sets forth specific immunogens or vaccines which the egg-producing animal was hyperimmunized

with; there is no description of what the other substance is. Therefore the written description is not commensurate in scope with the claims drawn to substances other than antibodies. Neither the specification nor the claims teach how to define substances other than antibodies. Neither the claims nor the specification teach how to obtain such substances other than antibodies comprised within the egg product. There is no guidance as to what the substances are; or what substances can or cannot be comprised within the egg product as claimed. The specification does not include structural examples of substances other than antibodies. Thus, the resulting egg product could result in a product not taught and enabled by the specification.

The specification does not provide evidence of what the substance is. Page 6 lines 18-25 states that the inventor believes that certain anti-diarrheal agents are elicited via the hyperimmunization process and that the agents are not believed to be antibodies. However the specification never states what the anti-diarrheal agents are. The specification does not state the identity or structural characteristics of the substances other than antibodies. Moreover, there is evidence that the not even one substance other than an antibody has been identified and/or classified. In view of the lack of evidence, it is apparent that Applicants were not in possession of one or more anti-diarrheal substances other antibodies comprised within the egg product, at the time of filing the instant application.

A skilled artisan cannot envision the detailed structure of the anti-diarrhea; substances, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The

bacterium itself, or a nucleic acid structure is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. The anti-diarrheal characteristics distinguish the substances only by what it does, i.e., by affect diarrheal symptoms, which are purely functional distinctions. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification and claims describe an egg product that comprises anti-diarrheal substances which are not antibodies, however this description does not describe the claimed substance itself.

See also, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Thus, in the absence of some structural characteristics of the substance, a substance described only by the fact that it is not an antibody fails to meet the written

description requirements. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Claims 3 and 5 are drawn to immunogens and immunogen-coding DNA consisting of mixtures thereof. The written description in this case only sets forth specific immunogens, therefore the written description is not commensurate in scope with the claims drawn to mixtures thereof. Neither the specification nor the claims teach how to define mixtures thereof. Neither the claims nor the specification teach how to obtain such mixtures. There is no guidance as to what the mixtures are; or what immunogens can or cannot be used in the mixtures thereof as claimed. The specification does not include structural examples of mixtures thereof. Thus, the resulting mixture could result in a complexes not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of specifically named immunogens, the skilled artisan cannot envision the detailed structure of the mixtures thereof, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that

it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus.

Therefore only the recited immunogens and immunogen-coding DNA and not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph.

3. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-8 are drawn to a method for treating and preventing diarrheal symptoms wherein the method comprises administering to the subject an effective amount of egg product comprising one or more anti-diarrheal agents that comprise a substance other than an antibody.

The specification fails to teach the identity of anti-diarrheal substances that are not antibodies. Page 6 of the instance specification states that the inventor believes that certain anti-diarrheal agents are elicited via the hyperimmunization process and that the agents are not believed to be antibodies. The specification further teaches

hyperimmunization procedures which are well known in the art. The steps that the instant applicants followed and the immunogens used are all well known in the art. It is noted that the specification never teaches what the identity of the substances that are not antibodies actually art. The specification does not teach the claimed substances comprised within the egg product. The specification fails to teach examples of an egg product when identifiable substances other than antibodies. Therefore, the specification fails to enable to a method for treating and preventing diarrheal symptoms wherein the method comprises administering to the subject an effective amount of egg product comprising one or more anti-diarrheal agents that comprise a substance other than an antibody.

Moreover, if egg product being administered is not enabled, then similarly the method of administering that egg product is not enabled. The specification lacks any written description of a structure or relevant identifying characteristics of a substance comprised within the egg product that is not an antibody sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. The specification fails to teach what the critical substances are which have the ability to treat or prevent anti-diarrheal symptoms. The specification does not provide evidence of what the substance is. The specification never states what the anti-diarrheal agents are. The specification does not state the identity or structural characteristics of the substances other than antibodies.

In absence of further guidance from Applicants, the skilled artisan would have to discover what the appropriate substances would be. Such experimentation requires

ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of a method for treating and preventing diarrheal symptoms wherein the method comprises administering to the subject an effective amount of egg product comprising one or more anti-diarrheal agents that comprise a substance other than an antibody.

No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict what the substances are, whether the substances work in combination to provide synergistic properties or if there is only one particular substance. Accordingly, one of skill in the art would be required to perform undue experimentation to use a method for treating and preventing diarrheal symptoms wherein the method comprises administering to the subject an effective amount of egg product comprising one or more anti-diarrheal agents that comprise a substance other than an antibody. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

4. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the egg product contains a substance other than an antibody. It is unclear whether the substance is an anti-diarrheal drug or a substance inherently

found in egg yolk products. Therefore the metes and bounds of the language are unclear and clarification is requested.

Prior Art

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Emery et al., (US Patent 5,420,253) teach a method for separating immunoglobulins from the yolk of an egg and modes of administration and the concentration of the egg product is about .25-20 grams per day where the doses will depend upon the type of animal, size and the like. Polson (US Patent 4,357,272) teaches recovering antibodies from egg yolk. Sterling et al., (US Patent 5,753,228) teach a method of treating parasitosis by enteral administration of hyperimmune hen egg yolk antibodies. Stolle et al., (US Patent 5,215,746) teach eggs obtained from animals hyperimmunized against at least one antigen. Tokoro (US Patent 5,080,895) teaches specific antibody containing substance produced from the egg if a hen where polyvalent antigens can be employed and these products are effective against diarrhea. Weiner et al., (US Patent 5,593,972) teach the use of genetic material as immunizing agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
April 2, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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